

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

1. (Currently amended) A vaginal or rectal applicator comprising

(a) an applicator barrel, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator, wherein the medication chamber is capable of containing 1 mL or less of a pharmaceutical composition, and wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber;

(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel;

(c) a plunger tip, wherein the plunger tip is at the end of the plunger; and

(d) an applicator cap, wherein the applicator cap is removable from the proximal end of the applicator barrel.

2. (Original) The vaginal or rectal applicator of claim 1, wherein the applicator further comprises a flange.

3. (Currently amended) The vaginal or rectal applicator of claim 1, wherein the applicator cap has a diameter that is effective at preventing insertion of the vaginal applicator into a vagina when the applicator cap is attached to the applicator barrel.

AMENDMENT AND RESPONSE TO OFFICE ACTION

4. (Original) The vaginal or rectal applicator of claim 1, wherein the applicator cap forms an air-tight seal with the applicator barrel.

5. (Original) The vaginal or rectal applicator of claim 1, wherein the plunger tip forms an air-tight seal with the applicator barrel.

6. (Currently amended) A method of transvaginal or transrectal drug delivery comprising

(1) placing breech filling a vaginal or rectal applicator with 1 mL or less of a pharmaceutical formulation in a vaginal or rectal applicator, wherein the vaginal applicator comprises

(a) an applicator barrel, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator, wherein the medication chamber is capable of containing 1 mL or less of a pharmaceutical composition;

(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel; and

(c) a plunger tip, wherein the plunger tip is at the end of the plunger;

(2) placing an applicator cap on the applicator barrel;

(3) removing the applicator cap from the proximal end of the applicator barrel; and

(4) inserting the applicator barrel into a patient's vagina or rectum.

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AMENDMENT AND RESPONSE TO OFFICE ACTION

7. (Original) The method of claim 6, wherein the pharmaceutical formulation is in a form selected from the group consisting of a powder, gel, cream, lotion, suppository, ovule, tablet, and capsule.

8. (Original) The method of claim 6, further comprising depressing the plunger to administer the pharmaceutical formulation to the region of the patient's upper vaginal vault or rectum.

9. (Currently amended) The method of claim 6, wherein the pharmaceutical formulation is in an amount effective to treat disorders and diseases ~~of the~~ of the female urogenital system, cervix, uterus, ovaries, fallopian tubes, peritoneal cavity, and lower abdominal cavity.

10. (New) The method of claim 6, further comprising depressing the plunger until it reaches the end of the applicator barrel.